

Art Unit 1811

15. Applicant's arguments have been fully considered, but have not been found to be convincing.

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. Claims 1-7 and 9-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 never recites that factor VIII:C is part of the solution. Factor VIII:C should be recited after "containing" in order to claim it properly as part of the solution.

18. Claims 1-7, 9-12 and 14 are rejected under 35 U.S.C. § 103 as being unpatentable over Meyers et al. (Meyers). Meyers discloses a large scale adaptation of a recently reported glycine precipitation method for the production of Factor VIII:C concentrate. This method includes adding aluminum hydroxide to a glycine buffer to reduce the level of protein contamination in the final preparation. Furthermore, the resultant product was virus-inactivated by the incorporation of the organic solvent and detergent (TNBP and T80) (abstract). At the industrial level, this method gave 185 IU of FVIII:C activity per liter of starting

Serial No. 08/23527/

-3-

Art Unit 1811

plasma, which the Examiner deems to be at least equivalent to Applicants' yield. Although he does not teach a pharmaceutical containing a solution, he does teach that his concentrate is considered to be suitable for clinical use (page 146, column 1, last 3 lines). Thus, the preparation of a solution with Factor VIII:C activity containing a basic amino acid such as glycine and a nonionic detergent containing a high activity for clinical use would have been obvious to one of ordinary skill in the art in the light of Meyer's disclosure.

19. Claim 13 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. § 112, second paragraph.

Any inquiry concerning this communication should be directed to P. Lynn Touzeau, Ph.D at telephone number (703) 308-0196.

PLT 16 May 1995


JILL WARDEN
SUPERVISORY PATENT EXAMINER
GROUP 1800